



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2016-0142; FRL-9966-13]

#### Triflumezopyrim; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of triflumezopyrim in or on rice, grain and rice, hulls. E.I. Dupont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective *[insert date of publication in the Federal Register]*.

Objections and requests for hearings must be received on or before *[insert date 60 days after date of publication in the Federal Register]*, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0142, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please

review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To

access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.”

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0142 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0142, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL-9944-86), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E8448) by E.I. Dupont de Nemours and Company, 974 Centre Road, Wilmington, DE 19805. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide triflumezopyrim (2,4-dioxo-1-(5-pyrimidinylmethyl)-3-[3-(trifluoromethyl)phenyl]-2*H*-pyrido[1,2-*a*]pyrimidinium inner salt), in or on rice, grain at 0.20 parts per million (ppm). That document referenced a summary of the petition prepared by E.I. Dupont de Nemours and Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance for rice, grain to 0.40 ppm based on the OECD tolerance calculation procedure. Additionally, EPA is requiring a tolerance for rice, hull at 1.0 ppm. The reason for these changes are explained in Unit IV.D.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for triflumezopyrim including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with triflumezopyrim follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and

children. The most common adverse effect observed across the triflumezopyrim toxicological database was a decrease in absolute bodyweight in dogs and rats in both sexes following subchronic and chronic exposures. No additional non-cancer effects relevant for human health risk assessment were noted in the subchronic rat and dog oral toxicity studies. No effects were seen in the mice and rabbit studies, including the dermal toxicity study.

Chronic exposures in rats resulted in an increased incidence of bile duct hyperplasia in the presence of decreases in absolute bodyweight (~70 milligrams/kilogram/day (mg/kg/day)). Additional lesions were seen in the liver, testes, and uterus at a higher dose (~400 mg/kg/day). The rat combined chronic/carcinogenicity study showed an increase in uterine and liver tumors at a dose of ~400 mg/kg/day, which is considered excessive for evaluating carcinogenic potential. The remaining doses were not considered excessive and did not show treatment-related tumors in either sex. Liver tumors in male mice during the mouse carcinogenicity study were considered treatment-related. The proposed mode of action (constitutive androstane receptor (CAR)-mediated proliferation) for the liver tumors in male mice was adequately supported by mechanistic data that clearly identified the sequence of events, dose-response concordance and temporal relationship for this tumor type. Triflumezopyrim is classified as “not likely to be carcinogenic to humans at dose levels that do not cause a significant induction in CYP2B activity.” Based on the mechanistic studies provided, significant induction in CYP2B only occurred at 7,000 ppm (727 mg/kg/day in male mice); the chronic reference dose used for the Agency’s safety assessment is based on a no observed adverse effect level of 17 mg/kg/day. As a result, the Agency concludes that the chronic reference dose

will be protective of potential carcinogenicity, which can be assessed through a non-linear approach. There is no mutagenicity concern based on the results from the *in vitro* and *in vivo* genetic toxicity studies.

Evidence of increased quantitative susceptibility in the rat developmental toxicity study was observed in the form of incomplete ossification of the parietal skull in the fetuses of dams treated with a relatively high dose (200 mg/kg/day) in the absence of any maternal toxicity. There was no evidence of susceptibility in the rat reproduction toxicity or rabbit developmental toxicity study.

Possible signs of neurotoxicity were observed in the acute neurotoxicity (ACN) in rats as well as in the 28-day subchronic oral toxicity study in dogs. An overall decrease in motor activity was observed in the ACN study on the day of dosing. Animals also showed slight decreases in body temperature and number of rearing movements, as well as increases in the incidence of high posture, at a dose 4x higher than what elicited the decrease in motor activity. The 28-day subchronic oral toxicity study in dogs showed neurobehavioral signs such as slight impairment of forelimb and/or hindlimb strength and effects on pupil constriction. However, the neurobehavioral signs were not seen in studies of longer duration in dogs.

Although evidence of neurotoxicity was seen in the ACN study in rats and 28-day oral toxicity study in dogs, concern is low since: 1) effects are well-characterized with clearly established NOAEL/LOAEL values; 2) no additional neurotoxic effects were seen in the toxicological database including the subchronic neurotoxicity study (SCN); 3) there were no corroborating neuropathological findings; 4) the neurobehavioral signs in

the dog were not observed in studies of longer durations in dogs; and 5) the selected endpoints for risk assessment are protective of these effects.

Specific information on the studies received and the nature of the adverse effects caused by Triflumezopyrim as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document Triflumezopyrim: Human Health Risk Assessment to Establish Tolerances for Rice Without U.S. Registration at page 21 in docket ID number EPA-HQ-OPP-2016-0142.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete



description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-human-health-risk-assessments-pesticides>.

A summary of the toxicological endpoints for Triflumezopyrim used for human risk assessment is shown in the Table below.

**Summary Table of Toxicological Doses and Endpoints for Triflumezopyrim for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 100 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	aPAD = 1.0 mg/kg/day	Acute neurotoxicity study (rats) LOAEL = 500 mg/kg/day based on decreased motor activity on day of dosing.
Chronic dietary (All populations)	NOAEL = 17 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	cPAD = 0.17 mg/kg/day	Combined chronic/carcinogenicity study (rats) LOAEL = 71/74 (M/F) mg/kg/day based on decreased absolute bodyweights in females and increased incidence of bile duct hyperplasia in males.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic to humans at dose levels that do not cause a significant induction in CYP2B activity. Quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>DB</sub> = to account for the absence of data or other data deficiency. UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>L</sub> = use of a LOAEL to extrapolate a NOAEL. UF<sub>S</sub> = use of a short-term study for long-term risk assessment.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to triflumezopyrim, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from triflumezopyrim in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for triflumezopyrim. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA). As to residue levels in food, EPA used an unrefined dietary analysis and incorporated tolerance-level residues and assumed 100% of all rice was treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 National Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA). As to residue levels in food, EPA used an unrefined dietary analysis and incorporated tolerance-level residues and assumed 100% of all rice was treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that triflumezopyrim is not likely to cause cancer to humans at dose levels that do not cause a significant increase in CYP2B activity. Additionally, there is no chronic risk from exposure to triflumezopyrim and the chronic reference dose is protective of potential carcinogenicity. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for triflumezopyrim. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Because there are no domestic registrations for triflumezopyrim in the United States, dietary exposure (acute and chronic) from imported commodities is the only source of exposure assessed. Residues from imported commodities are not expected to reach drinking water sources.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Triflumezopyrim is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found triflumezopyrim to share a common mechanism of toxicity with any other substances, and triflumezopyrim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that triflumezopyrim does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine

which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility in the rabbit developmental or the rat reproduction toxicity studies; however, there was evidence of increased quantitative susceptibility in the rat developmental study in rats where an increased incidence of incomplete ossification of the parietal skull was seen in the absence of maternal toxicity. Concern is low since: 1) the effect is well-characterized with clearly established NOAEL/LOAEL values; and 2) the selected endpoints for this chemical are protective of these effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for assessing risks for all populations. That decision is based on the following findings:

- i. The toxicity database for triflumezopyrim is complete.

ii. Although there is evidence of neurotoxicity in the ACN study in rats and 28-day oral toxicity study in dogs for triflumezopyrim, the concern is low since: 1) the effects are well-characterized with clearly established NOAEL/LOAEL values; 2) no additional neurotoxic effects were seen in the toxicological database including the SCN; 3) there were no corroborating neuropathological findings; 4) the neurobehavioral signs in the dog were not observed in studies of longer durations in dogs; and 5) the selected endpoints for this chemical are protective of these effects. As a result, there is no need to require a developmental neurotoxicity study or retain the 10X to account for potential neurotoxic effects.

iii. Although there was evidence of increased quantitative susceptibility in the rat developmental toxicity study where incomplete ossification of the parietal skull in the fetuses of dams treated with a relatively high dose (200 mg/kg/day) was observed in the absence of any maternal toxicity, concern is low since: 1) the effect is well-characterized with clearly established NOAEL/LOAEL values and 2) the selected endpoints for this chemical are protective of these effects. There was no evidence of increased susceptibility in the rabbit developmental or the rat reproduction toxicity studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on considering that 100% of all rice was treated and using tolerance-level residues. Since the metabolites were found at insignificant levels in the metabolism studies, triflumezopyrim is considered the only residue of concern. These assessments will not underestimate the exposure and risks posed by triflumezopyrim.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to triflumezopyrim will occupy < 1 % of the aPAD for all infants < 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to triflumezopyrim from food will utilize < 1 % of the cPAD for all infants < 1 year old, the population group receiving the greatest exposure. There are no residential uses for triflumezopyrim.

3. *Short-term and Intermediate-term risk.* Triflumezopyrim is not registered for any use patterns that would result in short-term or intermediate-term residential exposure. Because there are no residential uses for triflumezopyrim, as a result, aggregate risk estimates for short- and intermediate-term exposure are equivalent to the chronic dietary risk estimates and are not of concern.

4. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has determined that triflumezopyrim is not likely to be carcinogenic to humans at doses that do not cause a significant induction in CYP2B activity. Because there is no chronic

risk from exposure to triflumezopyrim and the chronic reference dose is protective of potential carcinogenicity, triflumezopyrim is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to triflumezopyrim residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (DuPont Liquid chromatography Mass spectrometry/mass spectrometry (LC/MS/MS) methods 36348 and 45170) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for triflumezopyrim.

### *C. Revisions to Petitioned-For Tolerances*

EPA is establishing a tolerance for rice, grain at 0.40 ppm, rather than at 0.20 ppm as requested, in addition to establishing a tolerance for rice, hulls of 1.0 ppm. The rice grain tolerance is based on the OECD tolerance calculation procedure with the inputted residues adjusted proportionally to reflect the maximum application rate. The raw agricultural commodity of “rice, grain” consists of the rice kernel, as well as the rice hull. The rice hull is considered a processed commodity for rice, and where residues concentrate in processed commodities, a higher tolerance to cover those residues is warranted. Because the available data indicates a higher level of residues on the rice hull, EPA is establishing a separate tolerance to cover those residues.

## **V. Conclusion**

Therefore, tolerances are established for residues of triflumezopyrim, (2,4-dioc-1-(5-pyrimidinylmethyl)-3-[3-(trifluoromethyl)phenyl]-2H-pyrido[1,2-a]pyrimidinium inner salt), in or on rice, grain at 0.40 and rice, hulls at 1.0 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject



to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition,

this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 7, 2017.

Richard P. Keigwin, Jr.,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.107 to subpart C to read as follows:

**§ 180.107 Triflumezopyrim; tolerance for residues.**

(a) *General.* Tolerances are established for residues of the insecticide triflumezopyrim, including its metabolites and degradates, in or on the following food commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only triflumezopyrim (2,4-dioxo-1-(5-pyrimidinylmethyl)-3-[3-(trifluoromethyl)phenyl]-2*H*-pyrido[1,2-*a*] pyrimidinium inner salt) in or on the commodity.

Commodity	Parts per million
Rice, grain*	0.40
Rice, hulls*	1.0

\* There are no U.S. registrations for the use of triflumezopyrim on these commodities.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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